

K042084

JUN 15 2005

**510(k) summary as described in § 807.92**

**510(k) Summary**

**Submitter:** **BioDerm Sciences, Inc.**  
Enterprise Center  
9 Industrial Park Drive, Suite 1N  
Oxford, Mississippi 38655  
Phone: (301) 216-3912

**Contact Person:** Ed Gubish Ph. D. <[egubish@bioderm Sciences.com](mailto:egubish@bioderm Sciences.com)>  
Chief Scientific Officer

**Preparation Date:** May 26, 2005

**Proprietary Device Name:** BioDerm Wound Spray

**Classification Name:** Liquid Bandage

**Predicate Devices:**

BioDerm Wound Solution	K040683
Dermagran wound cleanser with zinc	K945802
Restore Wound Cleanser	K040779

**Description:**

BioDerm Wound Spray is an acidic zinc-saline wet dressing for external wound management. It aids the body in the healing process by providing a moist, acidic wound environment. The non-irritating components of BioDerm Wound Spray allow it to be used in the mouth, eyes and on mucous membranes as well as on the skin.

BioDerm Wound Spray is similar in chemical composition to the previously cleared BioDerm Sciences Wound Solution with the spray also containing 0.002% of some trace elements. A difference between these products is that the predicate device BioDerm Sciences Wound Solution is supplied sterile in injection bottles, while the current device is supplied non-sterile in pump-spray bottles. The dressing is applied by spraying onto the affected area.

BioDerm Wound Spray is supplied in 100 ml spray bottles with a plunger activated pump applicator.

**Intended Use (Prescription):**

BioDerm Sciences Wound Spray is intended to cleanse, rinse and externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, partial

and full-thickness wounds, burns and ulcers (diabetic, venous stasis, pressure). It is meant to be used in conjunction with a sterile dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

Intended Use (OTC): BioDerm Sciences Wound Spray is intended to clean, rinse and externally manage skin wounds such as minor lacerations, minor cuts, minor burns and abrasions.

BioDerm Wound Spray can also be used as a wound cleanser to remove foreign matter, bacteria and tissue debris.

BioDerm Wound Spray is contraindicated for use when patients are known to have had allergic reactions to this dressing or its components. It is not suitable for use on third degree burns, or for any wound for which the dermis has been severely damaged or is missing.

Comparison of Technological Characteristics:

A number of wet dressings have been cleared for marketing by the FDA. All have in common that they are saline solutions based on sodium chloride or metallic salts with a pH less than or equal to 7 (i.e. acidic). They may or may not contain additives such as nutrients. BioDerm Wound Spray is supplied non-sterile.

A broad range of chemical compositions is currently available. The chemical composition of BioDerm Wound Spray is within the range of chemical compositions of these predicate devices and is substantially equivalent in terms of its safety and effectiveness. (See Table 1)

Performance:

A study of various formulations with varying strength levels of the metallic salts, performed at the University of Miami (Department of Dermatology & Cutaneous Surgery) using a porcine model demonstrated the effectiveness of BioDerm Wound Spray as an aid to the body's healing of burns, and partial wounds.

Conclusions:

When used as directed, BioDerm Wound Spray is safe and effective as a wound cleanser or wet dressing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Edward R. Gubish, Ph.D.  
Chief Scientific Officer  
BioDerm Sciences Incorporated  
Enterprise Center  
9 Industrial Park Drive, Suite 1N  
Oxford, Mississippi 38655

JUN 15 2005

Re: K042084  
Trade/Device Name: BioDerm Sciences Wound Spray  
Regulation Name: Saline wound dressing  
Regulatory Class: Unclassified  
Product Code: MUG  
Dated: May 17, 2005  
Received: May 18, 2005

Dear Dr. Gubish:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

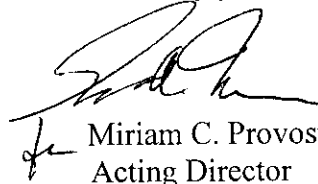
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Edward R. Gubish, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'M. Provost', is written over a horizontal line.

Miriam C. Provost, Ph.D.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K042084

### Indications for Use

510(k) Number: TBD

Device Name: BioDerm Sciences Wound Spray

#### Indications for Use:

BioDerm Sciences Wound Spray is intended to cleanse, rinse and externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, partial and full-thickness wounds, burns and ulcers (diabetic, venous stasis, pressure). It may also be used in conjunction with a dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).


Prescription Use X  
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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**Indications for Use**

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Device Name: BioDerm Sciences Wound Spray

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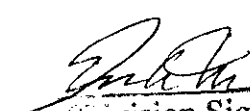
BioDerm Sciences Wound Spray is intended to clean, rinse and externally manage skin wounds such as minor lacerations, minor cuts, minor burns and abrasions.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use   X    
(21 CFR 807 Subpart C)

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BioDerm Sciences, Inc.